

## PATENT COOPERATION TREATY

## PCT


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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/US2004/017339	International filing date (day/month/year) 03.06.2004	Priority date (day/month/year) 03.06.2003	
International Patent Classification (IPC) or national classification and IPC G01N21/86, G01N21/25			
Applicant BAYER HEALTHCARE, LLC.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand  04.04.2005		Date of completion of this report  28.09.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer  Bockstahl, F  Telephone No. +31 70 340-3652	



**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/US2004/017339

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-17 as originally filed

**Claims, Numbers**

1-34 as originally filed

**Drawings, Sheets**

1/6-6/6 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing *(specify)*:
  - ☐ any table(s) related to sequence listing *(specify)*:
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing *(specify)*:
  - ☐ any table(s) related to sequence listing *(specify)*:

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	
	No: Claims	1-34
Inventive step (IS)	Yes: Claims	
	No: Claims	1-34
Industrial applicability (IA)	Yes: Claims	1-34
	No: Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents:

**D1:** WO 99/41596 A (77 ELEKTRONIKA M & UDBLAC ; FOELDVARI ZSOLT (HU); SUEMEGI LASZLO (HU)) 19 August 1999 (1999-08-19)

**D2:** EP-A-0 646 784 (MILES INC) 5 April 1995 (1995-04-05)

**D3:** EP-A-1 118 859 (WAKO PURE CHEM IND LTD) 25 July 2001 (2001-07-25)

**D4:** EP-A-0 837 320 (BAYER AG) 22 April 1998 (1998-04-22)

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **independent claims 1, 11, 14, 15, 25, 30, 33** is not new in the sense of Article 33(2) PCT.

2.1 The document **D1** discloses (see: abstract; figures 3-5; page 2, lines 13-19; page 3, line 29 - page 4, line 26; page 5, line 12 - page 7, line 29; page 9, lines 17-19; page 10, lines 14-29; page 11, line 23 - page 12, line 5; page 13, lines 1-3; page 13, line 20 - page 14, line 6):

a method of identifying a test strip having a set of test pads , said method comprising:

A. impinging on said set of test pads at least one test signal having a wavelength;

B. detecting a set of reflected signals from said set of test pads;

C. generating an image comprised of a set of reflectance values derived from said set of reflected signals;

D. determining a test pad type from the image for at least one test pad from the set of test pads by comparing a reflectance value associated with the test pad with a set of reference reflectance values, wherein each of said reference reflectance values corresponds to said wavelength and is associated with a different reference test pad type;

Furthermore, it is known for **D1** on page 6, lines 10-12 that: "*E.g. the colour recognition program may be programmed to detect automatically the **type of the test strip**, without the operator having to enter it into the apparatus separately.*"

Therefore **D1** also discloses feature E. of independent claim 1, i.e. to

E. identifying said test strip as a function of a set of determined test pad types.  
**D1** disclosing all features A. to E., the subject-matter of **independent claim 1** is therefore not new (Articles 33(1) and 33(2) PCT).

- 2.2 The same objection are raised against novelty of **independent claim 1** having regard to the disclosure of documents **D2** to **D4**, see the corresponding passages cited in the search report.
- 2.3 The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding **independent claims 11, 14, 15, 25, 30, 33**, which therefore are also considered not new.
3. **Dependent claims 2-10, 12, 13, 16-24, 26-29, 31, 32, 34** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see documents **D1** to **D4** and the corresponding passages cited in the search report.

#### **Re Item VII**

#### **Certain defects in the international application**

4. Although **claims 1, 11** (method claims) and **claims 14, 15, 25, 30** (system claims) have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.